

REMARKS

Applicants thank the Examiner for the courtesies she extended their attorney in the interview held on October 15, 2002. During this interview the Examiner questioned whether the negative limitation "but not the entirety of the cell wall" in claim 1 was supported by the specification. The Examiner stated that removing this limitation and specifying that one or more isolated components of the cell wall of *Mycobacterium* are administered to a mammal may overcome the prior art without the use of the negative limitation. Consistent with this discussion, claim 1 has been amended to specify that one or more isolated components of the cell wall of *Mycobacterium* are administered to a mammal. As discussed below, this amendment is supported by the specification and overcomes the rejection of claims 1-4 and 7-10 under 35 USC 112, first paragraph, made in the last office action dated June 10, 2002. This amendment does not necessitate a further search of the prior art and should be entered.

Claims 1-4 and 7-10 stand rejected under 35 USC 112, first paragraph, because the Examiner cannot find support for the limitation "but not the entirety of the cell wall," as recited in independent claim 1. This rejection is respectfully traversed. Claim 1 has been amended to remove this limitation. In addition, claim 1 has been amended to specify that the cell wall components are isolated cell wall components. Support for this limitation can be found throughout the specification.

For example, page 1, lines 9-12, of the specification states: "[e]ven more particularly, the present invention contemplates a method for preventing, delaying onset of or otherwise ameliorating the effects of insulin-dependent diabetes mellitus (IDDM) by administering a cell wall subunit . . ." (emphasis added). A subunit is an isolated part of a larger unit. Accordingly, administering a cell wall subunit is administering an isolated component the cell wall.

Another example can be found on page 3, lines 11-16, of the specification, which states: "[s]till yet another aspect of the present invention contemplates immunomodulatory therapy in a mammal said method comprising administering to said mammal an immunomodulatory effective amount of mycolyl-arabinogalactan-peptidoglycan (MAPG) or a component thereof with or

without other associated cell wall components and submolecular components . . .” (emphasis added). MAPG is a subunit of the cell wall of a Mycobacterium and does not comprise the whole cell wall. See specification page 7, lines 11-14, which states: “[t]he major components of the mycobacterium cell wall are: 1) mycolyl-arabinogalactan-peptidoglycan (MAPG), a polymer which provides the structural framework of the cell wall, 2) lipids, 3) phosphatidylinositol mannosides, and 4) lipoarabinomannan (LAM).” As stated in the specification, MAPG can be administered complete or broken down into smaller isolated components. Further, MAPG can **be isolated** allowing it to be administered **without** other cell wall components.

Since it is clear that the specification as originally filed supports the administration of one or more isolated components of the cell wall, the rejection of claims 1-4 and 7-10 under 35 USC 112 should be withdrawn.

For the foregoing reasons, early action allowing the claims in this application is solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned “**Version with markings to show changes made**”.

In the event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 229752000600.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Please amend claim 1.

1. (Twice Amended) A method of immunomodulatory therapy in a mammal said method comprising administering to said mammal an immunomodulating effective amount of one or more isolated components of the cell wall [, but not the entirety of the cell wall,] of *Mycobacterium*.